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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,981	01/25/2001	Aladar A. Szalay	13070-1	5416

7590 03/05/2003
SHELDON & MAK
Attn: David A. Farah, M.D.
225 South Lake Avenue, Suite 900
Pasadena, CA 90101

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,981

Applicant(s)

SZALAY ET AL.

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. David Farah made election on April 28, 2002 without traverse in a telephonic response. Claims 1-12 are under consideration in this office action.

Drawings

2. The drawings are objected to because of the reasons set forth in the attached PTOL-948. However, the corrections will not be held in abeyance and applicant must submit proposed drawing corrections in response to the requirement in the Office action.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. The use of the trademarks MAXI-PREP KITTM and BIORADTM on page 8 lines 24 and 28 and other reagents named throughout the specification have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method for evaluating whether a material will allow bacteria to pass through the material or around the material or into the material comprising: providing bacteria which are modified to produce a first signal; placing the bacteria on a first side of the material being evaluated; and determining whether the first signal is present on a second side of the material or within the material.

The claims are so broad that they encompass evaluating every type of material, however, applicants have not described such a method. The instant specification fails to

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provide: the identity of a class of materials which can be evaluated; there is no discussion of whether the material can be solid or porous to allow the bacteria to pass through, around or into the material. There is no limitation on the class of materials capable of being tested. If the material is antibiotic gauze or glass how can one of skill in the art tell if the bacteria passed around or through the material? If the bacteria dies, as a result of being in contact with the material, one cannot say whether the bacteria passed through the material or not. The method can only detect the modified bacteria; the method does not detect unmodified bacteria; however, there appears to be no correlation between the detection of bound modified bacteria and undetected yet bound unmodified bacteria. Thus, unmodified bacteria can pass through, around and into the material without being detected and the method could not therefore accurately evaluate the material. Moreover, if the modified bacteria fails to leave a fluorescent trail to demarcate its travel path, then one of skill in the art cannot assess where/how the bacteria traveled about the material; rather one can only say the bacteria did not attach itself to the material. Likewise, there is no teaching of how the bacteria will attach itself to the second side of the material in order to be detected. Does the material have some affinity for the bacteria or trap the bacteria based on size exclusion principles to determine whether the bacteria passed through, around or into the material? If the bacteria that fails to attach itself to the material but passes through, around or into the material, then the method steps are not commensurate in scope to a method for evaluation of whether or not a material will allow bacteria to pass through, around or into the material. Moreover, the steps are so broad that it is unclear how to determine a first

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or second side of a material. For instance, if the material is root repair material and placed in the hollow center space of the tooth as discussed in the example at page 9, which side is the first and second side?

Also, the specification does not teach what amount of bacteria is required to be in contact with the material to determine whether the bacteria passed through, around or into the material. There is no description of the type of materials that can or cannot be evaluated. There is no written description of any of the required method steps to evaluate whether a material will allow bacteria to pass through the material or around the material or into the material.

It is unclear that one of skill in the art could use the claimed method to evaluate whether a material will allow bacteria to pass through the material or around the material. The instant specification fails to provide a protocol that teaches method steps for such evaluation, furthermore, there is no data showing that such an evaluation will result in the determination of whether a material will allow a bacteria to pass through the material or around the material or into that material.

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of a method for evaluating whether a material will allow a bacteria to pass through the material or around the material or into the material as instantly claimed.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "first side" "second side" in the claims is relative terms, which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bound of the terms are broad thereby making the claims indefinite.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no detection step. The claims fail to positively recite how the first or second signal is detected on the second side of the material within the material. It is noted that determination of whether the first or second signal on the material is not equivalent to an actual detection step.

8. The preamble of claim 1 is drawn to a method for evaluating whether a material will allow a bacteria to pass through the material or around the material or into the material compromising: providing bacteria which are modified to produce a first signal; placing the bacteria on a first side of the material being evaluated; and determining whether the first signal is present on a second side of the material or within the material, however there the preamble of the claim must be drawn to the same method steps

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which are recited by the body of the claims. The claims are inconsistent since the body of the claim does not teach how to evaluate whether a material will allow bacteria to pass through, around or into the material, but rather determine whether the bacteria has attached itself to the material. The claims lack essential method steps drawn to evaluating whether bacteria has passed through, around or into the material. Therefore, the claims are incomplete.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
November 27, 2002


MARK NAVARRO
PRIMARY EXAMINER